

THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DAVID J. DEARINGER, *et al.*,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

CASE NO. C21-0060-JCC

ORDER

This matter comes before the Court on Plaintiffs' motion to certify a question to the Washington State Supreme Court (Dkt. No. 20). Having thoroughly considered the parties' briefing and the relevant record, the Court hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

Plaintiff David Dearinger alleges he suffered a subarachnoid hemorrhage or intracerebral hemorrhage leading to a paralytic stroke causing severe and permanent disabilities less than two hours after taking Cialis. (Dkt. No. 10 at 4–6.) The medication is a phosphodiesterase-5 enzyme inhibitor manufactured and sold by Defendant Eli Lilly and Company, used to treat benign prostatic hyperplasia, pulmonary arterial hypertension, and erectile dysfunction. (*Id.* at 1, 4.) Plaintiffs assert that Defendant knew or should have known that Cialis presented a risk of paralytic stroke to its users, yet it failed to adequately warn them of this risk. (*Id.* at 7–10.)

1 Plaintiffs sued under Washington’s Products Liability Act (“WPLA”), Chapter 7.72 of the
2 Revised Code of Washington, for negligent design, negligent failure to warn, and a breach of
3 warranty, along with a common law claim for loss of consortium. (*Id.* at 7–12.)

4 Defendant recently moved to dismiss Plaintiffs’ First Amended Complaint, arguing that,
5 based on the “learned intermediary” doctrine, the only relevant warning for purposes of
6 Plaintiffs’ suit was that to Mr. Dearinger’s prescribing physician, and that warning, describing a
7 risk of stroke, was adequate as a matter of law. (*See* Dkt. No. 14 at 10–14.) Defendant’s FDA-
8 approved physician prescribing information or label¹ describes the “serious cardiovascular
9 events, including . . . stroke” which have been identified during “post approval use of CIALIS.”
10 (Dkt. Nos. 15-1 at 10, 27-1 at 10.) However, Defendant’s FDA-approved *patient* information
11 insert only warns of a risk of stroke if Cialis “is taken with certain other medications.” (Dkt. Nos.
12 15-1 at 31, 27-1 at 23.) Therefore, to the extent that this warning label is relevant, a reasonable
13 jury could consider it to be inadequate.

14 Washington has adopted the “learned intermediary” doctrine, which limits a prescription
15 drug manufacturer’s duty to warn, as described in Washington’s product liability law, to the
16 prescribing physician. *See Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517, 524 (Wash. 2017).
17 However, as Plaintiffs point out, Washington courts have not addressed whether products like
18 Cialis that drug manufacturers widely market directly to consumers should be exempt from the
19 doctrine. (Dkt. No. 25 at 13–17.) Plaintiffs ask the Court to certify the following question to the
20 Washington Supreme Court:

21 Is a manufacturer, that promotes a prescription drug through “direct-to-consumer”
22 marketing, still exempt from warning the consumer of that drug’s dangerous side
23 effects under the “Learned Intermediary Doctrine” adopted by the State of

24 ¹ The label is referenced in Plaintiff’s complaint. (*See* Dkt. No. 7 at 10.) It is also publicly
25 available. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021368s029lbl.pdf.
26 Finally, its authenticity is not subject to reasonable dispute. Accordingly, the Court takes judicial
notice of the language contained within the label. *United States v. Ritchie*, 342 F.3d 903, 908–09
(9th Cir. 2003).

1 Washington in *Terhune v. A.H. Robins Co.*, 577 P.2d 925 (Wash. 1978)?
2 (Dkt. No. 20 at 2.)

3 **II. DISCUSSION**

4 A federal court may certify to the Washington Supreme Court a question of Washington
5 law involved in the underlying federal case when “it is necessary to ascertain the local law . . . in
6 order to dispose of such proceeding and the local law has not been clearly determined.” Wash.
7 Rev. Code § 2.60.020. The certification process serves the important judicial interests of
8 efficiency and comity. Certification “helps build a cooperative judicial federalism.” *Lehman*
9 *Bros. v. Schein*, 416 U.S. 386, 391 (1974).

10 The vast majority of state courts that have considered the issue have concluded that, in a
11 situation such as this one, the “learned intermediary” doctrine should apply. *See, e.g., Watts v.*
12 *Medicis Pharm. Corp.*, 365 P.3d 944, 950–51 (Ariz. 2016); *Centocor, Inc. v. Hamilton*, 372
13 S.W.3d 140, 162 (Tex. 2012). Nevertheless, not every state has. *See Perez v. Wyeth Labs. Inc.*,
14 734 A.2d 1245, 1260 (N.J. 1999). Washington is a unique state and application of the doctrine to
15 situations such as this one has far-reaching public policy and legal implications to Washington’s
16 consumers. Therefore, in the interest of judicial comity, the Court FINDS that certification is
17 appropriate.

18 Accordingly, the Court certifies Plaintiffs’ question, as articulated above, to the
19 Washington Supreme Court. The Court does not intend Plaintiffs’ framing of the question to
20 restrict the Washington Supreme Court’s consideration of any other issues that it determines are
21 relevant. Moreover, the Washington Supreme Court may, in its discretion, reformulate the
22 question in whatever manner it finds most appropriate. *See Affiliated FM Ins. Co. v. LTK*
23 *Consulting Servs. Inc.*, 556 F.3d 920, 922 (9th Cir. 2009).

24 **III. CONCLUSION**

25 For the foregoing reasons, Plaintiffs’ motion to certify a question to the Washington
26 Supreme Court (Dkt. No. 20) is GRANTED. The Clerk is DIRECTED to submit to the

1 Washington Supreme Court a certified copy of this order; a copy of the docket in the above-
2 captioned matter; and copies of Docket Numbers 10, 15-1, 20, 22, and 27-1. The record so
3 compiled contains all matters in the pending case deemed material for considering the certified
4 question. Plaintiffs shall file the opening brief on the certified question, in accordance with the
5 Washington Rules of Appellate Procedure. *See* Wash. R. App. P. 16.16.

6 Defendant's motion to dismiss (Dkt. No. 14) is STAYED until the Washington Supreme
7 Court either answers the certified question or affirmatively declines to do so. The Clerk is
8 DIRECTED to terminate all other case management deadlines. The parties are ORDERED,
9 within fourteen days of the Washington State Supreme Court's answer, or communication
10 declining to provide an answer, to move to lift the stay, to meet and confer, and to provide this
11 Court with a Joint Status Report.

12
13 DATED this 6th day of July 2021.

14
15
16
17
18
19
20
21
22
23
24
25
26

A handwritten signature in black ink, reading "John C. Coughenour", is written over a horizontal line.

John C. Coughenour
UNITED STATES DISTRICT JUDGE